

REMARKS/ARGUMENTS

This amendment is filed with a Request for Continued Examination and is in response to the action of March 28, 2008 in which claims 1, 3-17 and 48-50, comprising all of the claims pending in the application, were finally rejected and the advisory action of June 10, 2008. Claim 1 has been amended to more clearly define that the pledget is carried by the staple.

THE CITED REFERENCES

U.S. Patent 7,008,435 (Cummins)

Cummins discloses a surgical stapling device that includes a shaft said to have at its distal end a "bullet-like" head 26 shown in FIGS. 2 and 3 of the patent, reproduced below.

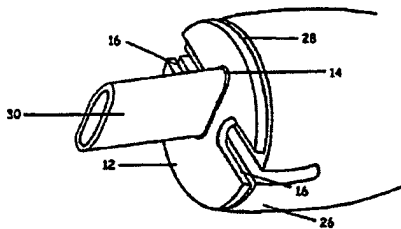


FIG. 2

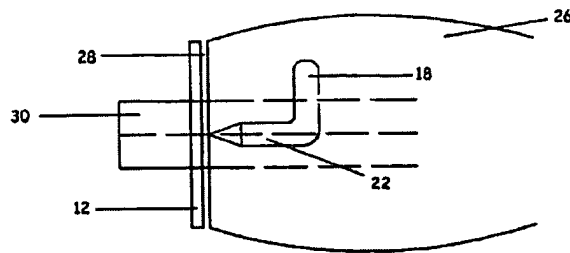


FIG. 3

A staple 18, 22 is housed within the head 26 in readiness to be ejected forwardly during the stapling procedure. The mechanism by which the staple 18, 22 is supported or advanced is not disclosed in the reference, although another publication is mentioned but is not incorporated by reference. A cap 12 (pledget) is disposed just forward of the forward end 28 of the head 26 and is held in place by being mounted on a blood locator tube 30 used in the preliminary positioning of the head 26 with respect to a puncture in a blood vessel. The undisclosed mechanism by which the device is said to operate, simultaneously advances the staple 18, 22 forwardly while retracting the blood locator tube 30 rearwardly. The cap 12 does not move and is disclosed as being held in place during the positioning of the device by its attachment to the blood locator tube. The cap 12 has a pair of slots 16 that are held in alignment with the legs 22

of the staple so that the legs can be driven through the slots 16 when the device is operated. The slots 16 are substantially wider than the legs 22 of the staple, as seen in FIG. 1, below.

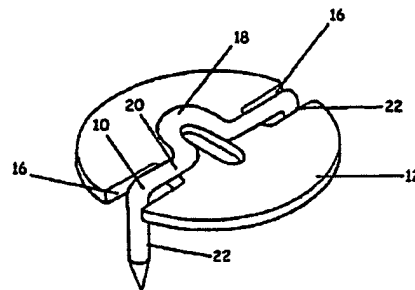


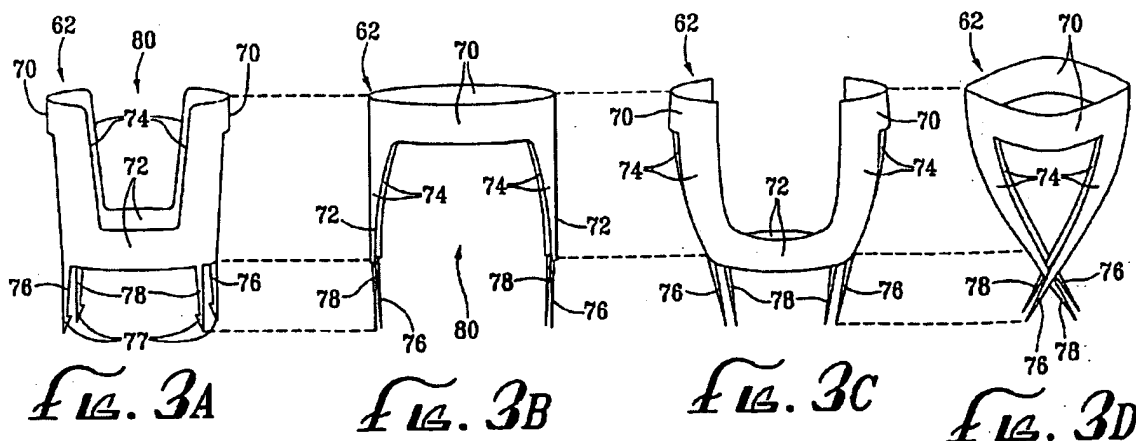
FIG. 1

U.S. Patent 6,273,897 (Dalessandro)

Dalessandro '897 has been cited for its disclosure of a bioabsorbable pledget containing physiologically active agents that are released over a predetermined time interval, antimicrobial or antiseptic agents, agents that inhibit intraluminal clotting or promote extraluminal clotting, or agents that comprise a coating or are impregnated in the pledget.

U.S. Patent 6,277,140 (Ginn)

Ginn discloses a vascular closure clip in the form of a resilient spring clip having an expanded (stressed) delivery configuration and an unstressed deployed configuration, as illustrated in FIGS. 3A-3D below:



The clip is advanced to the puncture site in the vessel while in the stressed configuration of FIGS. 3A and 3B. When the deployment device releases the stress, the clip returns to its relaxed, unstressed state of FIG. 3D, drawing tissues together. There is no disclosure or suggestion of a pledget.

CLAIM REJECTIONS – 35 U.S.C. §102

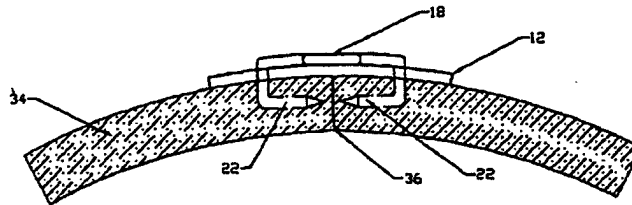
Reconsideration is requested of the rejections of claim 1, 3-8, 48 and 50 as anticipated by Cummins '435. Cummins fails to disclose a number of the limitations recited in claim 1 including:

- the proximal end of the staple being configured to enable the delivery device to control closure of the staple prongs solely by manipulation of the proximal end of the staple;
- the pledget being pre-attached to and carried by the staple;
- the pledget having edges configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple by engagement of the pledget edges with the prongs;
- the relationship between the prongs and pledget to enable the combined staple and attached pledget to be advanced together.

The failure of Cummins to disclose any one of the above demonstrates the impropriety of the rejection under 35 U.S.C. §102. Here, all of these features are missing from the reference.

First, Cummins makes no disclosure of how the prongs of the staple are closed. There is no disclosure of any arrangement by which the delivery device may control closure of the staple prongs solely by manipulation of the proximal end of the staple. If anything, Cummins states that the undisclosed closure device, somehow, "...bends the staple to bring the free ends of the legs 22 toward one another to close the staple, and finally release the closed staple." (3:61-65). There is no disclosure of a staple proximal end configured to enable staple closure solely by manipulation of the proximal end of the staple. Although Cummins refers to some kind of undisclosed staple-firing mechanism, it does not disclose a mechanism or a staple in which the staple prongs can be closed "solely by manipulation of the proximal end of the staple" as claimed. FIG. 6A of Cummins, reproduced below, is instructive. It discloses the configuration

of the staple after its legs have been closed, from which it should be apparent that the legs of the staple are bent. That would require some form of mechanism to bend the staple legs.



Applicants' claimed invention calls for the staple prongs being closable solely by manipulation of the proximal end of the staple. It may be noted that FIGS. 4 and 5 of Cummins, referred to in the comments appended to the advisory action, do not disclose a staple in which its prongs can be closed solely by manipulation of the proximal end of the staple.

Cummins also fails to disclose a pledget pre-attached to the staple. Claim 1 has been amended to further define that the pledget is carried by the staple. As is apparent from FIG. 3, there is no attachment or even contact between the staple and the pledget before they are brought to engagement with the tissue. There simply is no pre-attachment of any kind. There is no disclosure in Cummins of a pledget that is carried by a staple. FIG. 3 in Cummins does not disclose a pledget and staple that are attached in any manner, directly or indirectly. The pledget 12 is carried solely and only by the blood locator tube 30. FIG. 3 discloses no contact between the staple and the pledget and, as discussed above, the prongs 22 of the staple never contact any portion of the pledget 12 at any time. The only time the staple and the pledget make any contact is when the staple has been fully driven and its legs bent, at which time the hump 18 of the staple bears against the proximal surface of the pledget.

Moreover, FIGS. 1-6 do not, as suggested in the advisory action, disclose that the staple is driven into the pledget and that the staple and pledget together are driven into the tissue. While the "back" of the staple is eventually brought to bear against the surface of the pledget, the two are never advanced together and the pledget is not carried by the staple. Rather, the pledget is placed against the tissue and then becomes trapped between the tissue and the back of the staple when the staple is driven forward and crimped.

Additionally, Cummins does not disclose a pledget having edges configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple by engagement of the pledget edges with the prongs, with the pledget being carried by the staple. As is apparent from the drawings, the slots 16 and the cap 12 are considerably larger than the legs 22 of the staple. While they are arranged to allow the staple legs 22 to pass through the slots while the staple is driven into the tissue, there is no disclosed frictional engagement or claimed capturing of the pledget by engagement of the pledget edges with the prongs. Indeed, there is no apparent contact between the legs 22 and cap 12 at any time. To the extent that the action seeks to define the term "pre-attached" as being limited to "...before the staple engages tissue..." there is no basis for that interpretation. The claim is not so limited. In any case, Cummins fails to suggest a pledget pre-attached to, or even in contact with the staple at any time before the staple is finally cinched in place.

Finally, the relationship between the slot 16 and the staple legs 22 in Cummins does not enable the two to be combined and attached so as to be advanced together toward the arteriotomy with the pledget being carried by the staple. Cummins describes an operation in which only the staple is driven toward the free end 28 of the delivery device. While the disk 12 is said to become trapped between the closed staple and the tissue, there is no disclosure of the claimed relationship of the staple legs and the disk 12 (pledget). Indeed, Cummins describes that "...it is important that the staple legs 22 are positioned back in the staple head behind the disk 12 and not protruding beyond the free end 28 of the staple head." The staple head is said to be positioned "...behind the disk 12 at a distance at least equivalent to the length of the staple legs." (4:12-21).

Each of claims 3-8, 48 and 50 depends directly or indirectly from claim 1 and none is anticipated by Cummins '435 for the same reasons.

CLAIM REJECTIONS – 35 U.S.C. §103

The §103(a) Rejections Are Improper Because They Do Not Resolve and Articulate the Level of Skill That Was Applied

The finality of the action should be withdrawn. The action of March 28, 2008 was incomplete in that it failed to respond to applicants' challenge to the rejections under 35 U.S.C. §103. Those rejections did not resolve and articulate the level of skill that was applied. As

explained in applicants' traverse of December 19, 2007, one of the essential underlying factual elements that must be determined under the Supreme Court decisions of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) is that the level of skill must be resolved. The failure to indicate what level of skill was applied in the §103(a) rejections leaves insufficient basis to test the correctness of the rejection. A mere conclusory statement that claimed subject matter would have been obvious to one of ordinary skill provides no factual underpinning or support. The failure to articulate the level of skill is itself a basis for withdrawal of the rejection.

37 C.F.R. §1.104 requires that an examiner's action be complete as to all matters. See M.P.E.P. §707.07. An examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application. Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it. M.P.E.P. §707.07(f). Neither the present final rejection nor the previous rejection articulated any standard for the level of skill applied in making the obviousness rejections. That is contrary to *Graham v. Deere* and *KSR v. Teleflex*, supra. Applicant's traverse of the rejections under Section 103 has not been answered.

Reconsideration is requested of the rejection of claims 9-17 as obvious under 35 U.S.C. §103(a) in view of the combined disclosures of Cummins and Dalessandro '897. Claim 9 depends from claim 1 and includes all of the limitations discussed above in connection with claim 1. Cummins does not, as asserted, disclose the claimed device except for the pledget having a psychologically active agent. Dalessandro fails to disclose or suggest those features of applicants' invention that are missing from Cummins, discussed above. Thus, where neither Cummins nor Dalessandro can be considered as disclosing those missing features, their combination cannot be considered as doing so.

Reconsideration is requested of the rejection of claim 49 as obvious under 35 U.S.C. §103(a) in view of the combined disclosures of Cummins '435 in view of Ginn '140. Ginn has been cited for its disclosure of a staple with four prongs 76 commonly connected at a crown 70.

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Ginn fails to disclose those features of applicants' invention that are missing from Cummins as discussed above in connection with claim 1. Thus, where claim 49 includes all the limitations of claim 1 and where Ginn fails to disclose those features of applicants' invention that are missing from Cummins as described above, the rejection is improper.

Respectfully submitted,

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